IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

C.A. No
JURY TRIAL DEMANDED

COMPLAINT

Plaintiff DNA Genotek Inc. ("DNA Genotek"), by its attorneys, alleges as follows:

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 8,221,381 B2 ("the '381 patent") (attached as Exhibit A hereto).

PARTIES

- 2. Plaintiff DNA Genotek is a Canadian corporation with its principal place of business in Kanata, Ontario. DNA Genotek is a wholly-owned subsidiary of OraSure Technologies, Inc., a Delaware corporation with its principal place of business in Bethlehem, Pennsylvania.
- 3. Upon information and belief, Defendants Spectrum DNA, Spectrum Solutions L.L.C., and Spectrum Packaging, L.L.C. (collectively "Spectrum") are Utah limited liability companies with their principal place of business in Draper, Utah.

JURISDICTION AND VENUE

- 4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, Section 1, et seq. of the United States Code. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).
- 5. This Court has personal jurisdiction over Spectrum because it has purposefully availed itself of the privileges and benefits of the laws of the State of Delaware. Upon information and belief, Spectrum, its agents, subsidiaries, employees, and/or affiliates sell products in Delaware and ship products to Delaware that infringe the '381 Patent. Spectrum maintains at least two websites. It registered the domain name, www.spectrum-dna.com, on July 28, 2015. Spectrum also hired a marketing company that launched an additional website, through which Spectrum markets its DNA collection devices throughout the United States, including Delaware. On information and belief, before July 28, 2015, Spectrum concealed its making, using, selling, and offering for sale of the Spectrum product from DNA Genotek and much of the public. Spectrum, its agents, subsidiaries, employees, and/or affiliates target customers with ties to Delaware through at least one of their websites, which describes Spectrum as a company responding to a need "in the DNA space calling for an innovative saliva DNA collection device" and offering "an innovative device that is user friendly and produces excellent clinical results."
- 6. Upon information and belief, Defendant Spectrum Solutions L.L.C. manufactures at least one DNA saliva collection device that infringes the '381 Patent. Infringing products include Spectrum Model No. SS-SAL-1. Upon information and belief, Defendant Spectrum DNA sells and offers to sell DNA saliva collection devices that infringe the '381 Patent. Upon information and belief, Defendant Spectrum Packaging L.L.C. assembles and sells DNA saliva collection devices that are shipped in interstate commerce, including to Delaware, and that

infringe the '381 Patent.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

FACTUAL BACKGROUND

- 8. DNA Genotek is a leading provider of products for biological sample collection, including oral fluid sample collection and stabilization solutions for molecular applications.

 DNA Genotek has revolutionized the nucleic acid (DNA and RNA) collection market with products that provide substantial advantages over traditional methods of biological sample collection. DNA Genotek's products incorporate proprietary technology that is protected by a robust patent estate.
- 9. DNA Genotek developed and patented its proprietary saliva DNA collection kits ("DNA Genotek Saliva Collection Products"). DNA Genotek sells the DNA Genotek Saliva Collection Products to customers and distributors worldwide.
- 10. DNA Genotek is the owner by assignment of all right, title, and interest in and to United States Patent No. 8,221,381 B2 ("the '381 Patent"), entitled "Container System for Releasably Storing a Substance," which duly and legally issued to DNA Genotek, as assignee of Rod Muir, Derek Kirkland, Ian Curry, Roy Sunstrum, Paul Lem, and H. Chaim Birnboim, on July 17, 2012.
- District, alleging patent infringement, among other claims, because Ancestry offers for sale, sells, markets, and distributes a saliva collection device (the "Ancestry Product") that infringes the '381 Patent. Ancestry is a Delaware corporation that offers DNA testing services to customers researching their ethnic and family histories. Ancestry customers receive in the mail a DNA saliva collection kit and a return envelope to send the collection kit to a lab for DNA testing. After the testing, Ancestry sends the customer information about the customer's

ethnicity and relatives.

- 12. DNA Genotek has learned that the Ancestry Product is also made, used, offered for sale, marketed, distributed, and/or imported by Spectrum. Upon information and belief, Spectrum also makes, uses, offers for sale, markets, distributes, and/or imports products other than the Ancestry Product that infringe the '381 Patent, including the Spectrum Saliva Collection Kit (the "Spectrum Product").
- 13. Spectrum has been and is now infringing on one or more claims of the '381 Patent.
- 14. Spectrum infringes the '381 Patent at least by making, using, offering for sale, selling, marketing, distributing, and/or importing the Ancestry Product and/or the Spectrum Product.
- 15. Spectrum is infringing the '381 Patent, either literally or by the doctrine of equivalents.
- 16. Spectrum was aware of the '381 Patent when engaging in these knowing and purposeful activities and was aware that the making, using, selling, or offering for sale of the Ancestry Product or services incorporating the Ancestry Product constituted an act of infringement of the '381 Patent.
- 17. Spectrum was aware of the '381 Patent when engaging in these knowing and purposeful activities and was aware that the making, using, selling, or offering for sale of the Spectrum Product or services incorporating the Spectrum Product constituted an act of infringement of the '381 Patent.
- 18. Spectrum has been aware of the '381 Patent and the applications leading to the publication of the '381 Patent since at least November 14, 2014. The Spectrum Product is an

embodiment of a DNA saliva collection device depicted in PCT Patent Application No. WO 2015/017710 A1 (the "'701 Application"), entitled "Sample Collection Device," which was filed on July 31, 2014. On November 14, 2014, the patent office reviewing the '701 Application indicated that the device claimed in the '701 Application would be "easily conceived from the disclosure" two prior art references, including U.S. Patent Application Publication No. 20090216213 (the "'213 Application"). The '213 Application ultimately issued as the '381 Patent.

- 19. Ancestry is the owner by assignment of the '701 Application. The '701 Application lists Frederico Gaeta as an inventor. Frederico Gaeta has been employed, at least as a consultant, by both Ancestry, a Delaware corporation, and Spectrum.
- 20. Federico Gaeta is listed on the Spectrum website in conjunction with the development and production of the infringing Ancestry Product and/or the Spectrum Product.
- 21. Upon information and belief, Spectrum decided to make the infringing Ancestry Product and/or the infringing Spectrum Product after partnering with Ancestry, Spectrum's largest genotyping customer.
- 22. The Spectrum website indicates that the Ancestry Product and/or the Spectrum Product are labelled as "Patent Pending." The pending application that encompasses the embodiments of the Ancestry Product and/or the Spectrum Product is the '701 Application.
- 23. The Spectrum website includes a customer testimonial from an Ancestry employee and inventor listed on the '701 Application praising the company for its assistance in making, using, offering for sale, selling, marketing, distributing, and/or importing the Ancestry Product, which is offered for sale and sold in Delaware.
 - 24. On its website, Spectrum claims to have "[c]omplete fulfillment capabilities,"

including "[d]irect shipping" to customers. Examples of products shipped to the District of Delaware described on Spectrum's website include this device:



This is another example of the Spectrum Product described on Spectrum's website:



25. Spectrum's website identifies the Ancestry Product as one such product that it manufactures, sells, and ships. Upon information and belief, Spectrum offers for sale and/or ships the Ancestry Product and/or the Spectrum Product to customers throughout the country, including those located in or residing in Delaware.

26. Upon information and belief, apart from its sales of the Ancestry Product and/or the Spectrum Product to individuals throughout the country, including Delaware, Spectrum has offered for sale the Ancestry Product and/or the Spectrum Product to a least one other Delaware Corporation besides Ancestry, namely Complete Genomics Incorporated.

COUNT I – INFRINGEMENT OF THE '381 PATENT

- 27. DNA Genotek restates and incorporates by reference paragraphs 1-26, as if fully set forth herein.
- 28. Spectrum has been and is now infringing one or more claims of the '381 patent, either literally or by the doctrine of equivalents.
- 29. Spectrum's infringing activities include making, using, offering for sale, selling, marketing, distributing, and/or importing products that infringe one or more claims of the '381 Patent.
- 30. Spectrum infringes the '381 Patent at least by making, using, offering for sale, selling, marketing, distributing, and/or importing the Ancestry Product or services incorporating the Ancestry Product.
- 31. Spectrum infringes the '381 Patent at least by making, using, offering for sale, selling, marketing, distributing, and/or importing the Spectrum Product or services incorporating the Spectrum Product.
 - 32. Spectrum's infringing activities violate 35 U.S.C. § 271.
- 33. As a result of Spectrum's infringement of the '381 Patent, DNA Genotek has been and will be damaged, and DNA Genotek is entitled to be compensated for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial, but in no event less than a reasonable royalty.
 - 34. Upon information and belief, Spectrum's infringement of the '381 Patent has been

and continues to be willful and deliberate.

- 35. DNA Genotek has complied with any statutory requirement for placing a notice of its patents on its products, including but not limited to its Oragene•DNA®,

 Oragene•DISCOVER®, and Oragene•Dx® branded saliva collection kits.
- 36. Upon information and belief, Spectrum's infringement of the '381 Patent will continue unless enjoined by this Court. As a result of Spectrum's infringement, DNA Genotek has suffered and will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, DNA Genotek is entitled to injunctive relief against such infringement.
- 37. As a result of Spectrum's infringement, DNA Genotek has suffered and will continue to suffer significant damages.

PRAYER FOR RELIEF

WHEREFORE, DNA Genotek respectfully requests the following relief:

- (a) Entry of judgment that Spectrum has infringed the '381 patent;
- (b) Preliminary and permanent injunctive relief enjoining Spectrum, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with them, from directly or indirectly infringing the '381 patent;
- (c) An award of damages adequate to compensate DNA Genotek for Spectrum's infringement of the '381 patent;
- (d) An award of increased damages, under 35 U.S.C. § 284, in an amount three times the actual damages awarded to DNA Genotek, by reason of Spectrum's willful infringement of the '381 patent;
 - (e) A declaration that this case is exceptional under 35 U.S.C. § 285;
- (f) An award of DNA Genotek's costs and attorneys' fees incurred in connection with this action, under 35 U.S.C. § 285 and other applicable authority;

- (g) An award of pre-judgment interest; and
- (h) Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

DNA Genotek hereby demands trial by jury on all issues so triable.

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Dated: July 30, 2015

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